

ERC SYSTEM – Important Safety Information

WARNINGS:

Introduction (Chpt 1)

Read these operating instructions thoroughly before using the tubing clamp for the first time!

Safety (Chpt 2)

- In accordance with the applicable regulations, the tubing clamp is only intended to be used for clamping the arterial line. In case of alarm (bubble/level alarm or "negative flow"), the tubing clamp automatically clamps the arterial line. The tubing clamp is only intended for use with the Stöckert SCP System during cardiopulmonary bypass. Any use beyond this specification is not in accordance with the regulations and LivaNova Deutschland GmbH will not assume any liability for damage in such a case. Usage in accordance with regulations also includes compliance with the operating instructions, as well as repair and maintenance according to the maintenance instructions.
- Relevant accident prevention measures according to existing local policy and employees' health and safety regulations must be complied with. LivaNova Deutschland GmbH will not accept any liability for damage due to non-compliance with these regulations.
- LivaNova Deutschland GmbH will not assume any liability for injuries and/or damage caused by failure to observe the safety instructions or by the operator not taking due care. This also applies if the operator's duty to take due care has not been specifically expressed to the user.
- Basically, the tubing clamp is subject to the safety guidelines of the system it is used with.
- The tubing clamp is only intended for use with the SCP System. It must be positioned behind the pump head outlet at the arterial line.
- Prior to working with the SCP System, the user must have thoroughly read the separate operating instructions and have become familiar with the device functions
- When in operation, the tubing clamp and the SCP System must be monitored at all times. Noncompliance with this duty may result in danger to the patient's health! The safety features incorporated in the SCP System, e.g. audible alarm signals, are intended to aid the operator, but do not exempt the operator from carefully monitoring the system during operation.
- Prior to working with the tubing clamp, the user must have thoroughly read the operating instructions and have become familiar with the device functions
- Observe the perfusion process continually to ensure that you can change the tubing clamp adjustments according to the individual requirements at any time.
- For safety reasons, always have a haemostat/surgical clamp available and ensure that the arterial line is accessible when operating the electrical remote-controlled tubing clamp.
- Ensure that the clamping lever is clearly visible.
- Only use 3/8" x 3/32" PVC tubings for the tubing clamp.
- The temperature of the inserted tubing must be at least +15 °C.
- The tubing clamp must, under no conditions, be used as a replacement for an arterial filter.

- A minimum distance of 1.00 m (3.1 feet) between the bubble sensor and the patient must be ensured (using the same tubing diameter for the entire length of perfusion).
- Modifications or extensions to the tubing clamp, as well as the use of spare parts and accessories which have not been tested and approved by LivaNova Deutschland GmbH, may have negative effects on the safety and function of the system. LivaNova Deutschland GmbH cannot assume any liability or responsibility in such cases.

Overview and Installation (Chpt 3)

- In case of a power failure, the UPS of the SCPC System or the respective heart-lung-machine takes over the power supply of the tubing clamp and the SCP System.
- Charged and properly functioning batteries are a precondition for the safe operation of the system.

Operation (Chpt 4)

- Please read the following chapter thoroughly before operating the tubing clamp for the first time.
- The tubing clamp must, under no conditions, be used as a replacement for an arterial filter.
- For safety reasons, always have a haemostat/surgical clamp available and ensure that the arterial line is accessible.
- Basically, the arterial line must be clamped until the pump runs with the set speed in order to prevent return (negative) flow from the patient.
- Prior to working with the SCP System, the user must have thoroughly read the separate operating instructions and have become familiar with the device function
- Ensure that the swivel arm is holding the tubing clamp securely.
- The cause of this alarm must be traced back in order to avoid a possibly dangerous situation.
- The tubing clamp must not be reopened before having cleared the alarm.

Routine Maintenance (Chpt 5)

Cleaning:

- Only use lint-free cloths which have been moistened with water.
- Always wipe off spills (blood, etc.) from the tubing clamp as quickly as possible.
- Never use cleaning agents containing oil or grease. → Never use acetone-based cleaning agents as these may damage varnished surfaces or surfaces made of plastics.
- If possible, avoid cloth which causes static (polyester etc.).
- Liquids must not enter the housing. Therefore, do not use sprays.
- ▶ Disinfecting:
 - Only use alcohol-based hospital-grade hand disinfectants.
 - Only use lint-free cloth moistened with disinfectant.
 - Ensure again that no liquids enter the housing.

Cleaning and disinfecting the swivel arm:

- The instructions and information concerning the cleaning and disinfection of the overall system apply to the swivel arm at all times. In addition:
 - Ensure that the clamping lever is secured before cleaning and disinfecting.
 - Make sure that no liquid enters the joint of the swivel arm. Loosen the clamping lever if necessary. Use compressed air to blow out the joint carefully or leave the joint to dry.
 - Check the function of the swivel arm after cleaning and disinfecting.

CAUTIONS:

Overview and Installation (Chpt 3)

- Opening fast clamp connectors: Always hold on to the mounted clamping head before opening the fast clamp connector

Operation (Chpt 4)

- Only open the tubing clamp if negative flow can be excluded "Negative flow" can be excluded if the pressure in the arterial line is somewhat higher than the patient's systemic average pressure.

Routine Maintenance (Chpt 5)

- The instructions for routine maintenance, given in the following sections, are part of the operating conditions for the tubing clamp

For professional use. Please [click here](#) to find instructions for use containing full prescribing information, including indications, contraindications, warnings, precautions and adverse events. Consult your labeling.